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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,221	04/29/2008	Kazuei Igarashi	75954-010400/US	5977

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GREENBERG TRAURIG LLP (LA)
2450 COLORADO AVENUE, SUITE 400E
INTELLECTUAL PROPERTY DEPARTMENT
SANTA MONICA, CA 90404

EXAMINER

SHEN, BIN

ART UNIT	PAPER NUMBER
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1657

NOTIFICATION DATE	DELIVERY MODE
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08/02/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/599,221	Applicant(s) IGARASHI ET AL.	
	Examiner BIN SHEN	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4 and 6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4 and 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 April 2008 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/11/2009, 2/8/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The IDS received 8/11/2009, 2/8/2010, preliminary amendments received 9/22/2006, 10/16/2006 have been entered.

Election

Applicant's election **without** traverse of aldehyde compound as species, in the reply filed on 6/7/2010 is acknowledged.

Claims 2, 5, 7, 8 are cancelled

Only claims 1, 3, 4, 6 are presented for examination on the merits.

Benefit of priority is to 3/25/2004.

Acrolein is also known as 2-propenal, which is spontaneously formed from 3-aminopropanal during the oxidation of polyamine (see below Sakata 2003).

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Method of diagnosing apoplectic stroke/asymptomatic brain infarction using acrolein content.

Drawings

The drawings are objected to because Figures 3 and 4 are not clear/recognizable. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the

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renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for aldehyde compound that is acrolein, does not reasonably provide enablement for any and all aldehyde compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The art of biotechnology is a highly unpredictable art and it would be an undue burden for one of ordinary skill in the art to test any and all aldehyde compounds to see if they can be used as diagnosing marker for stroke/asymptomatic cerebral infarction. There is no prior art known to this examiner that establishes that one of ordinary skill in the art would have known at the time the invention was made that all or any of the aldehyde compounds can be used as diagnosing marker for stroke/asymptomatic cerebral infarction.

Applicant has only shown acrolein content in plasma of patients with brain disorder, see specification Example 1 on page 9. With only knowing the result of aldehyde compound produces acrolein, it is clear that such broad claims are not enabled by the instant specification when one of ordinary skill in the art is only given one particular aldehydy compound-acrolein that function as diagnosing marker for stroke/asymptomatic cerebral infarction.

The state of the art is that there is no art. Without any reference to all aldehyde compounds that function as diagnosing marker for stroke/asymptomatic cerebral infarction, one

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of ordinary skill in the art would have no way of knowing if all or any of the aldehyde compounds can be used as diagnosing marker for stroke/asymptomatic cerebral infarction.

Claims 1, 4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for plasma as biological sample from subject, does not reasonably provide enablement for any and all biological sample because not all/any biological sample has polyamine and the enzyme that converts polyamine to aldehyde compound for measurement. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The art of biotechnology is a highly unpredictable art and it would be an undue burden for one of ordinary skill in the art to test any and all biological sample to see if they can be used to measure aldehyde compound. There is no prior art known to this examiner that establishes that one of ordinary skill in the art would have known at the time the invention was made that all or any of biological sample can be used to measure aldehyde compound to diagnose stroke/asymptomatic cerebral infarction.

Applicant has only shown plasma as biological sample, see specification Examples 1-4 starting page 9. With only knowing the result of plasma as biological sample, it is clear that such broad claims are not enabled by the instant specification when one of ordinary skill in the art is only given one particular biological sample (plasma) for measurement for the diagnose of stroke/asymptomatic cerebral infarction.

The state of the art is that there is no art. Without any reference to all biological sample for aldehyde compound measurement to function as diagnosing marker for stroke/asymptomatic cerebral infarction, one of ordinary skill in the art would have no way of knowing if all or any of the biological sample can be used to measure aldehyde compound content to diagnose stroke/asymptomatic cerebral infarction because not all biological sample contain polyamine and the enzyme that convert polyamine to aldehyde compound.

Thus, the claims are unduly broad and do not find proper support from the instant specification. Thus, the rejection is properly made.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 4, 6 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claims 1, 4 are incomplete because it lacks information about how the sampling/measuring/diagnosing is accomplished; especially a correlating step to accomplish the preamble is missing as how the diagnosis/screening is made (what is the control? How the measured value is compared and used in the diagnosis? Etc.).

Claim 4 is rejected because the method is screening for patient, however the sample is taken from subject, should the sample be taken from patient that the method is screening?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 4, 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Els (2001, IDS submitted 2/8/2010), Ivanova (1998), and Sakata (2003, IDS submitted 2/8/2010).

Els et al. teach a diagnostic method for stroke comprising: sampling biological sample from subject by using blood samples from patients (see page 43, right column, 1st full paragraph), measuring polyamine in the sample (page 44, left column, 3rd paragraph), diagnosing/screening stroke by correlating the polyamine/spermidine level with clinical outcome and infarct volume (page 45, left column, 1st full paragraph and Fig. 2, part of **Claims 1 & 4**).

Els does not teach that the aldehyde compound measured is acrolein.

Ivanova teaches the oxidation of polyamine that generates 3-aminopropanal during the onset of cerebral ischemia (page 330, right column, end of 1st full paragraph).

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Sakata et al. teach the spontaneous formation of acrolein (**Claims 3 & 6**) from 3-aminopropanal: product of the oxidation of polyamine (page 371, left column 1st and 2nd paragraphs).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Els by measuring acrolein as aldehyde compound (**Claims 1, 3, 4, 6**) in samples from subjects to diagnose/screen for stroke/asymptomatic cerebral infarction because Els teaches that polyamine can be used as diagnose marker for stroke, Ivanova teaches the oxidation of polyamine to produce 3-aminopropanal during onset of cerebral ischemia, and Sakata teaches the spontaneous formation of acrolein from 3-aminopropanal. One would have been motivated to make the modification because Els et al. specifically described the correlation of polyamine/spermidine level with clinical outcome and infarct volume (page 45, left column, 1st full paragraph and Fig. 2), and Sakata et al. teaches the spontaneous formation of acrolein from 3-aminopropanal: product of the oxidation of polyamine (during onset of cerebral ischemia as taught by Ivanova), and would reasonably have expected success in view of both Ivanova and Sakata's teachings.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

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Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3, 4, 6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2 of copending Application No. 12598125. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claiming detecting/diagnosing method of stroke/asymptomatic cerebral infarction by measuring aldehyde compound content.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowed.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Bin Shen, whose telephone number is (571) 272-9040. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to her office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at (571) 272-0925.

B Shen

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/Karen Cochrane Carlson/

Primary Examiner, Art Unit 1656